K091060
1/2

SEP 23 2009

SECTION 5 – 510(k) Summary

Name, Address, Phone and Fax Number of Applicant

Owner: Stephen Holmes
Address: Vesocclude Medical, LLC
Durham, NC
Phone: 919-215-2717

Contact Person

Name: Diane Peper
Telephone: 919-570-9605
E-mail: dianepeper@gmail.com
Address: Triangle Quality Solutions, Inc.
10419 Stallings Road
Spring Hope NC 27882

Date Prepared: March 16th 2009

A. **Device Name**

Trade Name: Vesocclude Ligating Clip
Common Name: Hemostatic Clip, Ligating Clip
Classification Name: Vascular Clip

B. **Predicate Device**

Teleflex Medical Horizon Ligating Clips (510ks; K901303, K982313)
Teleflex Medical Hemoclip Ligating Clips (510ks; K841547, K841548, K841549)
Teleflex Medical Atrauclip Ligating Clips (510k; K861992)

C. **Device Description**

Vesocclude ligating clips are permanent implant, non-absorbable, sterile, surgical clips made from an implantable grade of Titanium and are available in multiple sizes.

Indications for Use

Vesocclude ligating clips are intended for use in procedures involving vessels or anatomic structures for which the user determines ligating clips are the best choice. Users should select the size and amount of the clips based on upon their experience, judgment, and needs.

Contraindications

This product is not intended for use as a contraceptive tubal occlusion device. This product is contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

D. **Characteristic Comparison to Predicate Device Equivalence**

The Vesocclude ligating clips are substantially equivalent to the predicate device in design (Chevron shaped clip), material (Titanium), performance characteristics and intended use. The Vesocclude ligating clips are specifically designed to be used with both the Teleflex Medical Horizon ligating clip and Vesocclude ligating clip appliers.

The technique used to transfer both the Vesocclude and Teleflex Medical Horizon ligating clip from plastic cartridge carrier into the jaw of the reusable stainless steel applier is the same. See Appendix 7 for photographs. Clip application to the ligation site is identical to the predicate device.

E. **Summary of Non-clinical Performance Data**

Vesocclude ligating clips are made of an implantable grade of Titanium with similar dimensions and metallurgical characteristics as the Teleflex Medical Horizon ligating clips. A metallurgical comparative analysis demonstrates that the Vesocclude ligating clips are as safe, as effective and perform as well as the predicate device. See Appendix 4 for additional details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 23 2009

Vesocclude Medical, LLC
% Triangle Quality Solutions, Inc.
Ms. Diane Pepers
10419 Stallings Roadn
Spring Hope, North Carolina 27882

Re: K091060
Trade/Device Name: Vesocclude Ligating Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: September 1, 2009
Received: September 4, 2009

Dear Ms. Pepers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091060

SECTION 4 – Indications for Use

510(k) Number:

Device Name: Vesocclude Ligating Clip

Indications For Use: Vesocclude ligating clips are intended for use in procedures involving vessels or anatomic structures for which the user determines ligating clips are the best choice. Users should select the size and amount of the clips based on upon their experience, judgment, and needs.

Contraindications: This product is not intended for use as a contraceptive tubal occlusion device. This product is contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

Prescription Use __Yes__ AND/OR Over-The-Counter Use _____

(PLEASE DOE NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091060